



Substitute for Form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 7

**Complete if Known**

Application Number	10/565029
Filing Date	September 11, 2006
First Named Inventor	Rose
Art Unit	1751
Examiner Name	
Attorney Docket Number	39262/324491

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US-3,531,561	09-29-1970	Trebu	
		US-3,636,956	01-25-1972	Schneider	
		US-3,736,646	06-05-1973	Schmitt	
		US-3,797,499	03-19-1974	Schneider	
		US-4,137,921	02-06-1979	Okuzumi	
		US-4,181,983	01-08-1980	Kulkarni	
		US-4,523,591	06-18-1985	Kaplan	
		US-4,539,981	09-10-1985	Tung	
		US-4,636,215	01-13-1987	Schwartz	
		US-4,938,763	07-03-1990	Dunn, et al.	
		US-5,108,755	04-28-1992	Daniels, et al.	
		US-5,192,301	03-09-1993	Kamika	
		US-5,266,608	11-30-1993	Katz, et al.	
		US-5,275,601	01-04-1994	Gogolewski, et al.	
		US-5,333,624	08-02-1994	Tovey	
		US-5,360,448	11-01-1994	Thramann	
		US-5,364,400	11-15-1994	Rego, Jr., et al.	
		US-5,417,712	05-23-1995	Whittaker	
		US-5,437,918	08-01-1995	Taniguchi	
		US-5,441,515	08-15-1995	Khosravi	
		US-5,470,334	11-28-1995	Ross, et al.	
		US-5,562,704	10-08-1996	Tamminmaki, et al.	
		US-5,633,002	05-27-1997	Stricker	
		US-5,634,936	06-03-1997	Linden	
		US-5,660,846	08-26-1997	Cheikh	
		US-5,670,161	09-23-1997	Healy	
		US-5,690,671	11-25-1997	McGurk	
		US-5,695,497	12-09-1997	Stahelin	
		US-5,716,410	02-10-1998	Wang, et al.	
		US-5,716,413	02-10-1998	Walter, et al.	
		US-5,733,330	03-31-1998	Cox	
		US-5,760,118	06-02-1998	Sinclair	
		US-5,766,239	06-16-1998	Cox	
		US-5,766,618	06-16-1998	Laurencin, et al.	
		US-5,792,400	08-11-1998	Talja, et al.	
		US-5,834,582	11-10-1998	Sinclair	
		US-5,837,276	11-17-1998	Camevale	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

2

of

7

**Complete if Known**

Application Number

10/565029

Filing Date

September 11, 2006

First Named Inventor

Rose

Art Unit

1751

Examiner Name

Attorney Docket Number

39262/324491

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US-5,893,850	04-13-1999	Cachia	
		US-5,904,658	05-18-1999	Niederauer, et al.	
		US-5,908,918	06-01-1999	Chen	
		US-5,968,092	10-19-1999	Buscemi	
		US-5,980,564	11-09-1999	Stinson	
		US-6,001,100	12-14-1999	Sherman, et al.	
		US-6,001,101	12-14-1999	Augagneur, et al.	
		US-6,005,161	12-21-1999	Brekke, et al.	
		US-6,113,624	09-05-2000	Bezwada, et al.	
		US-6,160,084	12-12-2000	Langer, et al.	
		US-6,162,225	12-19-2000	Gertzman, et al.	
		US-6,203,573	03-20-2001	Walter, et al.	
		US-6,248,108	06-19-2001	Tormala	
		US-6,283,973	09-04-2001	Hubbard, et al.	
		US-6,293,950	09-25-2001	Lynch, et al.	
		US-6,344,496	02-05-2002	Niederauer, et al.	
		US-6,375,465	04-23-2002	Engman, et al.	
		US-6,436,136	08-20-2002	Flodin, et al.	
		US-6,468,277	10-22-2002	Justin, et al.	
		US-6,503,278	01-07-2003	Pohjonen	
		US-6,511,511	01-28-2003	Slivka, et al.	
		US-6,514,286	02-04-2003	Leatherbury, et al.	
		US-6,565,606	05-20-2003	Bruce, et al.	
		US-6,652,582	11-25-2003	Stinson	
		US-6,783,712	08-31-2004	Slivka, et al.	
		US-6,841,111	01-11-2005	Rickner, et al.	
		US-6,916,321 B2	07-12-2005	TehHuisen, et al.	
		US-7,033,603	04-25-2006	Nelson, et al.	
		US-7,261,734	08-28-2007	Gellman, et al.	
		US-7,261,716	08-28-2007	Strobel, et al.	
		US-7,268,205	09-11-2007	Williams, et al.	
		US-7,270,813	09-18-2007	Shimp, et al.	
		US-2002/0029043	03-07-2002	Ahrens, et al.	
		US-2003/0114937 A1	06-19-2003	Leatherbury, et al.	
		US-2003/0125745	07-03-2003	Tseng, et al.	
		US-2004/0193154 A1	09-30-2004	Leatherbury, et al.	
		US-2004/0241203 A1	12-02-2004	Shakesheff, et al.	
		US-2004/0258732	12-23-2004	Shikinami	
		US-2004/0267263	12-30-2004	May	
		US-2004/0260398	12-23-2004	Kelman	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

3

of

**Complete if Known**

Application Number

10/565029

Filing Date

September 11, 2006

First Named Inventor

Rose

Art Unit

1751

Examiner Name

Attorney Docket Number

39262/324491

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2004/0265385	12-30-2004	West	
		US-2005/085313	04-21-2005	Nishitani	
		US-2005/0008672	01-13-2005	Winterbottom, et al.	
		US-2005/0013793	01-20-2005	Beckham, et al.	
		US-2005/0159812 A1	07-21-2005	Dinger, III, et al.	
		US-2005/0165128	07-28-2005	Cohn, et al.	
		US-2005/0177245 A1	08-11-2005	Leatherbury, et al.	
		US-2005/0209705 A1	09-22-2005	Niederauer, et al.	
		US-2005/0240281 A1	10-27-2005	Slivka, et al.	
		US-2006/0067973 A1	03-30-2006	Schachter	
		US-2006/0136071	06-22-2006	Maspero, et al.	
		US-2006/0188547	08-24-2006	Bezwarda	
		US-2006/0200150	09-07-2006	Homaki, et al.	
		US-2006/0178748 A1	08-10-2006	Dinger, III, et al.	
		US-2006/0247610 A1	11-02-2006	Lanphere, et al.	
		US-2006/0263335	11-23-2006	France, et al.	
		US-2007/0041950 A1	02-22-2007	Leatherbury, et al.	
		US-2007/0043376 A1	02-22-2007	Leatherbury, et al.	
		US-2007/0128154	06-07-2007	Hadba, et al.	
		US-2007/0134305	06-14-2007	Zilberman	
		US-2007/0191963 A1	08-16-2007	Winterbottom, et al.	
		US-2007/0240281 A1	10-27-2005	Slivka, et al.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

4

of

7

**Complete if Known**

Application Number

10/565029

Filing Date

September 11, 2006

First Named Inventor

Rose

Art Unit

1751

Examiner Name

Attorney Docket Number

39262/324491

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		WO 1990/003768	04-19-1990	Southern Research Institute		
		WO 1995/034331 A1	12-21-1995	Aoforschungsinstit ut Davos		
		WO 1997/005193 A1	02-13-1997	Sanitaria Scaligera Spa		
		WO 1998/026814 A1	06-25-1998	JVS-Polymers Oy		
		WO 1999/011297 A2	03-11-1999	Univ. of Nottingham		
		WO 2001/096105 A2	12-20-2001	Owens Corning Fiberglass Corp.		
		WO 2002/076725	10-03-2002	Sicc		
		WO 2005/085313 A1	09-15-2005	Commonwealth Scientific and Industrial Research Organization		
		WO 2006/053936	05-26-2006	JVS Polymers Oy		
		WO 2006/064025	08-24-2006	Fidia Advanced Biopolymers		
		WO 2007/065074 A2	06-07-2007	Indiana Univ. Res. And Tech. Corp.		
		WO 2007/084609 A2	07-26-2007	Osteotech, Inc.		
		EP 0 204 931 B2	12-17-1986	Biocon Oy		
		EP 0 401 844 B1	12-12-1990	Boehringer Ingelheim International		Claims
		EP 0 439 892 A2	08-07-1991	Kingston Technologies, Inc.		
		EP 0 531 487 B1	01-10-1996	Storch		Claims
		EP 1 056 487 B1	12-06-2000	MIT		
		EP 1 093 774 B1	06-19-2002	Karl Storz GmbH		Claims
		JP 2169612	06-29-1990	Asahi Chemical Ind.		Abstr
		JP 8196617	08-06-1996	Takiron Co.		Abstr
		JP 9040761	02-10-1997	Shimadzu Corp.		Abstr
		JP 9095606	04-08-1997	Shinetsu Chemical Co.		Abstr
		JP 9234241	09-09-1997	Shimadzu Corp.		Abstr
		JP 9272790	10-21-1997	Shimadzu Corp.		Abstr
		JP 9221539	08-26-1997	Shimadzu Corp.		Abstr
		JP 10176039	06-30-1998	Kanebo Ltd.		Abstr
		DE 39 36 188 A1	05-03-1990	Boehringer Ingelheim		Abstr
		DE 42 26 465 A1	02-11-1993	Gunze Ltd.		Abstr
		KR 141988 B1	06-15-1998	Samyang Co. Ltd.		Abstr

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered.  
Include copy of this form with next communication to applicant.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 5 of 7

**Complete if Known**

Application Number	10/565029
Filing Date	September 11, 2006
First Named Inventor	Rose
Art Unit	1751
Examiner Name	
Attorney Docket Number	39262/324491

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Andriano, et al., 'Processing and characterization of absorbable polylactide polymers for use in surgical implants,' <i>Journal of Applied Biomaterials</i> , 5(2):133-140 (1994)	
		Asano, et al., 'In vivo characteristics of low molecular weight copoly(D,L-lactic acid) formulations with controlled release of LH-RH agonist,' <i>Biomaterials</i> , 10(8):569-573 (1989)	
		Barca, et al., 'Resorbable poly-L-lactic acid mini-staples for the fixation of Akin osteotomies,' <i>The Journal of Foot and Ankle Surgery</i> , 36(2):106-111 (1997)	
		Bertrand, et al., 'Biocompatibility Aspects of New Stent Technology,' <i>JACC</i> , 32(3):562-571 (1998)	
		Celikkaya, et al., 'Poly(DL-lactide)/Poly(ethylene glycol) Copolymer Particles. I. Preparation and Characterization,' <i>Journal of Applied Polymer Science</i> , 61:1439-1446 (1996)	
		Frenger, 'Biomedical Uses of Shape Memory Polymers,' <i>Biomed. Sci. Instrum.</i> , 29:47-50 (1993)	
		Fukuzaki, et al., 'Synthesis of copoly(D,L-Lactic acid) with relatively low molecular weight and in vitro degradation,' Japan Atomic Energy Research Institute, Gunma, Jpn, <i>European Polymer Journal</i> , 25(10):1019-1026 (1989)	
		Giardino, et al., 'Experimental evaluation of a resorbable intramedullary plug for cemented total hip replacement,' <i>Biomaterials</i> , 18(13):907-913 (1997)	
		Gautier, et al., 'Poly(D-hydroxyacids) for application in the spinal cord: Resorbability and biocompatibility with adult rat Schwann cells and spinal cord,' <i>Journal of Biomedical Materials Research</i> , 42(4):642-654 (1998)	
		Haers, et al., 'Biodegradable polylactide plates and screws in orthognathic surgery,' <i>Journal of Cranio-Maxillofacial Surgery</i> , 26(2):87-91 (1998)	
		Kaitian, et al., 'Poly(D,L-Lactic Acid) Homopolymers: Synthesis and Characterization,' <i>Turkish Journal of Chemistry</i> , 20:43-53 (1996)	
		Kister, et al., 'Effects of morphology, conformation and configuration on the IR and Raman spectra of various poly(lactic acid)s,' <i>Polymer</i> , 39(2): 267-273 (1998)	
		Koelling, et al., 'In vitro real-time aging and characterization of poly(L/D-lactic acid),' <i>Proceedings of the 1997 16<sup>th</sup> Southern Biomedical Engineering Conference</i> (Cat. No. 97 <sup>TH</sup> 8270), pp. 197-201	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered.  
Include copy of this form with next communication to applicant.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

6

of

7

**Complete if Known**

Application Number

10/565029

Filing Date

September 11, 2006

First Named Inventor

Rose

Art Unit

1751

Examiner Name

Attorney Docket Number

39262/324491

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Kontio, et al., 'Fibrous wound repair associated with biodegradable poly-L/D-lactide copolymers implants: study of the expression of tenascin and cellular fibronectin,' <i>Journal of Materials Science-Materials in Medicine</i> , 9:10:603-609 (1998)	
		Kricheldorf, et al., 'Polyactones: 32. High-molecular weight polylactides by ring-opening polymerization with dibutylmagnesium or butylmagnesium chloride,' <i>Polymer</i> , 36(15):2995-3003 (1995)	
		Losken, et al., 'Memory of DL-poly(lactic acid) biodegradable plates,' <i>Ann. Plast. Surg.</i> , 32(6):606-611 (1994)	
		MacDonald, et al., 'Enzymatic degradability of poly(lactide): Effects of chain stereochemistry and material crystallinity,' <i>Macromolecules</i> , 29(23):7356-7361 (1996)	
		Mainil-Varlet, et al., 'Effect of in vivo and in vitro degradation on molecular and mechanical properties of various low-molecular weight polylactides,' <i>Journal of Biomedical Materials Research</i> , 36(3):360-380 (1997)	
		Matsumura, et al., 'Novel ring opening polymerization of lactide by lipase,' <i>Macromol. Symp.</i> , 130:285-304 (1998)	
		Morita, et al., 'Intravitreal delivery of dexamethasone sodium <i>m</i> -sulfobenzoate from poly(DL-lactic acid) implants,' <i>Biological &amp; Pharmaceutical Bulletin</i> , 21(2):188-190 (1998)	
		Okihara, et al., 'Crystal structure of stereocomplex of poly(L-lactide) and poly(D-lactide), <i>Journal of Macromolecular Science-Physics</i> , B30(1-2):119-140 (1991)	
		Penning, et al., 'Preparation and properties of absorbable fibres from L-lactide copolymers,' <i>Polymer</i> , 34(5):942-951 (1993)	
		Rak, et al., 'The preparation and characterization of poly(DL-lactic acid) for use as a biodegradable drug carrier,' Liverpool Polytech., Liverpool, UK, <i>Pharmaceutica Acta Helveticae</i> , 60(5-6):162-169 (1985)	
		Ristic, et al., 'An investigation of synthesis and degradation of poly(D,L-lactide) and controlled release of albumin from biodegradable poly(D,L-lactide) cylinders,' ICheaP-2, the second Italian conference on chemical and process engineering, Florence, pp. 559-563 (1995)	
		Schliephake, et al., 'Reconstruction of the mandible by prefabricated autogenous bone grafts,' <i>Int. J. Oral Maxillofac. Surg.</i> , 26:244-252 (1997)	
		Stahelin, et al., 'Clinical degradation and biocompatibility of different bioabsorbable interference screws: a report of six cases,' <i>Arthroscopy: The Journal of Arthroscopic &amp; Related Surgery</i> , 13(2):238-244 (1997)	
		Steendam, et al., 'The role of elastic relaxation in drug delivery from poly(DL-lactic acid) based tablets. A shape memory phenomenon,' <i>Proceedings of the International Symposium on Controlled Release of Bioactive Materials</i> , 25:128-129 (1998)	

Examiner  
Signature

Date

Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered.  
Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 7 of 7

**Complete if Known**

Application Number	10/565029
Filing Date	September 11, 2006
First Named Inventor	Rose
Art Unit	1751
Examiner Name	
Attorney Docket Number	39262/324491

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Stevens, et al., 'Blends van blok copolymeren die een poly(L-lactide) of poly(D-lactide) blok bevatten,' Biomedical Science and Engineering Meeting, pp. 107-110 (1994)	
		Tschakaloff, et al., 'Degradation kinetics of biodegradable DL-polyactic acid biodegradable implants depending on the site of implantation,' <i>International Journal of Oral and Maxillofacial Surgery</i> , 23(6 Pt2 ):443-445 (1994)	
		Tsuji, et al., 'Stereocomplex formation between enantiomeric poly(lactic acid). VIII. Complex fibers spun from mixed solution of poly(D-lactic acid) and poly(L-lactic acid), <i>Journal of Applied Polymer Science</i> , 51(2):337-344 (1994)	
		Zegzula, et al., 'Bone Formation with Use of rhBMP-2 (Recombinant Human Bone Morphogenetic Protein-2,' <i>The Journal of Bone and Joint Surgery</i> , 79:1778-1790 (1997)	
		Zhang, 'Biodegradable lactide polymers: synthesis, degradation, and controlled drug release properties (drug release), Queen's University at Kingston, Canada, Volume 55/01-B of Dissertation Abstracts International, p. i-xv, 1-179 (October 1993)	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.